SEP 15 2011

# 510(k) Summary

## Light Age, Inc. Q-Clear™ Nd:YAG Laser

**Submittal Information:**

Post Approval Contact:
Dr. Donald F. Heller, Chief Executive Officer
Elizabeth Reddington, Director of Regulatory Affairs
Light Age, Inc.
500 Apgar Drive
Somerset, NJ 08873
Tel: 732-563-0600
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**Device Name and Classification:**

| | |
|---|---|
| 510(k) Number: | K110370 |
| Proprietary Name: | Light Age Q-Clear™ Laser System |
| Common Name: | Nd:YAG Laser System |
| Classification Name: | Class IV Laser Surgical Instrument |
| Classification Panel: | General & Plastic Surgery Devices |
| C.F.R. Section | 878.4810 |
| Device Class: | II |
| Product Code: | GEX |

**Predicate Devices:**

- Light Age Q-Clear™ Laser [K033259], manufactured by Light Age, Inc., 500 Apgar Drive, Somerset, NJ 08873
- Pinpointe FootLaser™ [K093545 and K093547], manufactured by Pinpointe USA, Inc, 275 Airpark Boulevard, Suite 100, Chico, CA 95973
- Cutera GenesisPlus Laser System [K103626], manufactured by Cutera, Inc., 3240 Bayshore Blvd., Brisbane, CA 94005
- Palomar Q-YAG 5™ Nd:YAG Laser System [K061436], manufactured by Palomar Medical Technologies, Inc. 82 Cambridge Street, Burlington, MA 01803
- Family of Altus Medical CoolGlide Aesthetic Lasers [K022226], manufactured by Altus Medical, Inc. 821 Cowan Road, Burlingame, CA 94010

**Description:**

The Light Age Q-Clear™ laser has an Nd:YAG crystal rod as a lasing medium. Pulsed energy is emitted at 1064 nanometers in the infrared portion of the spectrum. With the frequency doubler installed, a 532nm beam is emitted. The 532nm emission is visible green light. Energy from the laser is delivered directly to the target area via the handpiece, which produces a circular beam on the skin. A red aiming beam is provided to allow the operator to precisely target the treatment area. The Q-Clear™ Laser is equipped with safety features in conformance with 21 CFR Part 1040.

The Q-Clear™ Nd:YAG laser system is comprised of the following main components:

(1) Main Console consists of electrical components including
   a. Control and Display Panel with
      - Keyswitch controlling access to the system and mode of operation (off, standby and ready)
      - Emergency Stop Button
   b. Remote Interlock Connector
   c. Footswitch connector
   d. Power Cord connector
(2) Footswitch
(3) Medical grade power cord
(4) Q-Switched 1064 / 532 nm Treatment Head with Nd:YAG laser rod
(5) Long Pulsed 1064 nm Treatment Head with Nd:YAG laser rod
(6) Delivery Devices intended for Non-Contact and contact with intact skin / tissue
   a. Handpieces
   b. Handpiece tips
(7) Operator and Patient safety glasses and goggles
(8) Accessories – standoffs, water bottle

**Indications For Use:**

The Light Age, Inc. Q-Clear™ Nd:YAG Laser System is intended for use in general and plastic surgery, dermatology, and podiatry for the incision, excision, vaporization of soft tissues. The Light Age, Inc. Q-Clear™ Nd:YAG Laser is indicated for the following uses:

The 1064nm wavelength is indicated for :

1. Podiatry – for incision, excision, vaporization, coagulation of soft tissues including:
   - Matrixectomy
   - Warts including periungual, subungual, and plantar warts
   - Radical nail excision
   - Neuromas
   - The Q-Clear™ Laser System is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes,* and/or yeasts *Candida albicans, etc.)*

2. Dermatology and Plastic Surgery - for incision, excision, vaporization, coagulation of soft tissues including:
   - Lesions of the skin and subcutaneous tissue
   - Spider veins
   - Plantar Warts
   - Periungual and subungual warts
   - Debridement of decubitus ulcer
   - Treatment of keloids

3. General Dermatology
   - Dark ink tattoo removal
   - Treatment of pigmented lesions (particularly Nevus of Ota)
   - Removal or lightening of hair
   - Skin resurfacing with or without adjuvant preparation
   - Treatment of common Nevi

The 532 nm wavelength is indicated for:

1. Dermatology and Plastic Surgery - for incision, excision, vaporization, coagulation of soft tissues including:
   - Spider veins
2. General Dermatology
   - Removal of light ink (red, tan, purple, and orange) tattoos
   - Treatment of common nevi
   - Treatment of café-au-lait spots
   - Treatment of seborrheic keratoses
   - Treatment of vascular lesions, including facial and leg veins, telangiectasias, angiomas, hemangiomas, port wine stains, and most pigmented lesions (e.g. lentigines, and ephelides)

**Summary of Clinical Tests:**

Light Age, Inc.'s study of 100 randomized subjects of both genders, including Caucasian, Asian, African American, and Latino, has demonstrated substantially effective clearance of dystrophic toenails having a clinically apparent diagnosis of onychomychosis. Statistical analysis of results indicates significant apparent clearing in 95% of the subjects with an average clearance of affected areas of 56±7% at 98% level of confidence. The protocol employed was extremely well tolerated by patients, no pain was reported, although some patients reported feeling a low-level sensation on some involved toenails. Reported patient satisfaction was 100%. No significant adverse reactions or responses were observed or reported.

The Q-Clear™ Laser System is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes,* and/or yeasts *Candida albicans, etc.)*

**Performance Standards:**

- The Q-Clear™ Nd:YAG Laser System complies with applicable performance standards for light emitting products as outlined in 21 CFR1040.10 and 21 CFR1040.11.

- The device also conforms to the voluntary electrical equipment standards: IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-1-22.

**Summary of Technological Characteristics:**

The technological characteristics of the Q-Clear™ Nd:YAG Laser system with the Long Pulse (LP) Head is substantially equivalent to the predicate device, having performance parameters within the latter's characteristic envelope – see table below:

| Characteristic | Current Submission | | Predicate Device A | Predicate Device B | Predicate Device C |
|---|---|---|---|---|---|
| | Q-Clear™ Nd:YAG | | Pinpointe FootLaser™ (K093547) | Family of Altus CoolGlide™ Aesthetic Lasers (K022226) | Palomar Q-YAG 5™ Nd:YAG Laser System (K061436) |
| Lasing Medium | Nd:YAG rod | | Nd:YAG rod | Nd:YAG rod | Nd:YAG rod |
| Aiming Beam | 630-680 nm ( ≤ 2.5mW) | | 630-680 nm ( ≤ 2.5mW) | Yes | Yes |
| Wavelength | 1064nm | 1064 / 532nm | 1064 nm | 1064 / 532nm | 1064 / 532nm |
| Model | LP | Q-Switched | "6W" Pinpoint Foot Laser | CoolGlide™ | Q-YAG 5™ |
| Maximum Power (Watts) | 6W | 6W | 6W | 14W | 4W |
| Maximum Energy Per Pulse | 200mJ | *400mJ | 200mJ | 7J | 400mJ |
| Maximum Pulse Duration | 100-200 µsec | 3 – 10 nsec | 100-3000 µsec | 0.1-300msec | 3 nsec |
| Output mode | Pulsed, multi-mode | Pulsed, multi-mode | Pulsed, multi-mode | Pulsed, multi-mode | Pulsed, multi-mode |
| Repetition Rate | 1 – 5 Hz | 1 – 5 Hz, Variable | 5-100 Hz | Single shot, up to 2 Hz | 1-10 Hz |
| Laser Media | Flashlamp - Pumped solid state laser rod | | Flashlamp – Pumped solid state laser rod | Flashlamp – Pumped solid state laser rod | Flashlamp – Pumped solid state laser rod |
| User interface | Push button control panel | | Push button control panel | Push button control panel | Push button control panel |
| User Activation | Footswitch | | Footswitch | Footswitch | Finger or Footswitch |
| Delivery Devices (How supplied) | Non-sterile, reusable, cleanable, sterilizable | | Non-sterile, reusable, cleanable, sterilizable | Non-sterile, reusable, cleanable, sterilizable | Non-sterile, reusable, cleanable, sterilizable |

| Characteristic | Current Submission<br>Q-Clear™ Nd:YAG | Predicate Device A<br>Pinpointe FootLaser™ (K093547) | Predicate Device B<br>Family of Altus CoolGlide™ Aesthetic Lasers (K022226) | Predicate Device C<br>Palomar Q-YAG 5™ Nd:YAG Laser System (K061436) |
|---|---|---|---|---|
| System Dimensions | 10" x 14" x 16" ( H x W x D) | 32" x 13"x 14"(H x W x D) | 12" x 19" x 35" (W x D x H) | 18" (45.7 cm) L x 19" (48.3 cm) H x 17" (43.2 cm) D |
| System Weight | 16 Kg (35 lbs) | 17.2 kg (38 lbs) | 61 kg (135 lbs) | Upper Module, 35 lbs. (15.8 kg); Lower Module, 35 lbs. (15.8 kg); Arm, <15 lbs. (6.8 kg); Handpiece, <3 lbs. (1.4 kg) |
| Electrical Requirements | 120/220-240VAC 50/60Hz; 10/5A; Single Phase | 90-130 VAC 50/60 Hz<br>200-240 VAC, 50/60 Hz | 110-230V 50/60 Hz | 100 – 240V, 50/60Hz |

* Maximum Energy Per Pulse is set by the levels below:
  Level 1 is equivalent to 350 mJ/Pulse.
  Level 2 is equivalent to 500 mJ/Pulse.
  Level 3 is equivalent to 600 mJ/Pulse.
  Level 4 is equivalent to 725 mJ/Pulse.

**Substantial Equivalence**

The reason for this 510(k) is based on new indications for use. Light Age, Inc. is adding new indications for use to our existing Q-Clear™ Nd:YAG laser system that has been cleared and in use since 2003 with no FDA reportable events.

The Light Age Q-Clear™ Nd:YAG Laser is substantially equivalent to the predicate devices listed above (Light Age Q-Clear™ Laser (K033259), Pinpointe FootLaser™ (K093547), Family of Altus CoolGlide™ Aesthetic Lasers (K022226), and the Palomar Q-YAG 5™ Nd:YAG Laser System (K061436)), with the same wavelengths, the same principles of operation, and essentially the same fluence levels. The differences in the specifications between the Q-Clear™ and the predicate device does not raise new questions of safety or efficacy.

**Safety and Effectiveness:**

The Light Age, Inc. Q-Clear™ Nd:YAG Laser System should not raise any concerns regarding its overall safety and effectiveness. In the nearly seven (7) years of use with over 500,000 treatments performed the Q-Clear™ Nd:YAG Laser has been proven to be clinically safe with no reports of significant patient or operator injury.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

Light Age, Inc.
% Ms. Elizabeth Reddington
Director of Regulatory Affairs
500 Apgar Drive
Somerset, New Jersey 08873-1150

Re: K110370
Trade/Device Name: Q-Clear™ Nd:YAG Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: PDZ, GEX
Dated: September 09, 2011
Received: September 12, 2011

Dear Ms. Reddington:

This letter corrects our substantially equivalent letter of September 15, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT:

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   - Treatment of keloids
3. General Dermatology
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   - Treatment of vascular lesions, including facial and leg veins, telangiectasias, angiomas, hemangiomas, port wine stains, and most pigmented lesions (e.g. lentigines, and ephelides)

(Division Sign-Off)
Division of Surgical, Orthopedic and Restorative Devices

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510(k) Number K110370 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____X____ OR Over the Counter Use _____
(Per 21 CFR 801.109)